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Implants Chirurgicaux

MAY 17 2013

510(k) Summary of Safety and Effectiveness information
Special 510(k) Premarket Notification – Salto Talaris Total Ankle Prosthesis, RHS

Date prepared: May 17th 2013

Regulatory authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1) Device name

Trade name: *Salto Talaris Total Ankle Prosthesis*
Common name: Total Ankle Prosthesis
Classification name: Ankle joint metal/polymer semi-constrained cemented prosthesis

Trade name: *RHS*
Common name: Radial Head Prosthesis
Classification name: Elbow joint radial (hemi-elbow) polymer prosthesis
 Elbow joint metal/polymer semi-constrained cemented prosthesis

2) Submitter

Tornier SAS
 161, Rue Lavoisier
 38330 Montbonnot Saint Martin - France

3) Applicant

Tornier SAS
 161, rue Lavoisier
 38330 Montbonnot Saint Martin - France

4) Company contact

Tornier SAS
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5) Classification

For the Salto Total Ankle Prosthesis:

Device class: Class II
Classification panel: Orthopedic
Product code: 87 HSN

For the RHS:

Device class: Class II
Classification panel: Orthopedic
Product code: JDB & KWI

6) Equivalent / Predicate device

For the Salto Talaris Total Ankle Prosthesis:

Salto Talaris Total Ankle Prosthesis, Tornier, K060544, K090076
 Alvine Total Ankle Prosthesis (Agility), DePuy, K920802, K020541
 Topez Total Ankle Replacement, Topez Orthopedics, Inc., K051023

For the RHS:

Radial Head Prosthesis, Tornier, K994041, K060438
 Radial Head, Avanta, K023604
 Explor, Biomet, K051385

7) Device description

For the Salto Talaris Total Ankle Prosthesis:

The goal of total ankle replacement is to restore function and relieve pain. The Salto Talaris Total Ankle Prosthesis is intended to accomplish these goals. The Salto Talaris Total Ankle Prosthesis is a semi-constrained anatomical design, which reproduces the kinematics of the ankle joint.

The Tornier Salto Talaris Total Ankle Prosthesis consists of two mating components: a metal tibial base in association with a conforming polyethylene articulating insert, and a metal talar resurfacing component.

For the RHS:

The RHS has been designed in order to provide surgeons and patients with a joint prosthesis to restore function and relieve pain of the radial part of the elbow joint. The RHS has an anatomical design, which reproduces the kinematics of the radial joint. The RHS consists of two components: a metal radial stem and a metal-polyethylene radial head.



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The present submission corresponds to the following modification:

- Addition of a new coating subcontractor (titanium coating): Eurocoating S.p.A on cobalt chromium components.

All the prostheses of this application are strictly identical to the previously cleared devices except for the coating supplier. The indications for use of each device are not modified.

8) Materials (modified components)

For the Salto Talaris Total Ankle Prosthesis:

The tibial and the talar components are manufactured from cobalt chromium alloy (CoCr) according to ISO standard 5834-2.

The titanium coating conforms to the ASTM standard F1580.

For the RHS:

The short stem is manufactured from cobalt chromium alloy (CoCr) according to ISO standard 5832-7 or ISO 5832-12.

The titanium coating conforms to the ASTM standard F1580.

9) Indications

Salto Talaris Total Ankle Prosthesis:

The Salto Talaris Total Ankle Prosthesis is indicated as a total ankle replacement in primary or revision surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

Components are intended for cemented use only.

RHS:

The RHS is intended for:

- 1) Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with:
 - a. Joint destruction and/or subluxation visible on x-ray
 - b. Resistance to conservative treatment
- 2) Primary replacement after fracture of the radial head
- 3) Symptomatic sequelae after radial head resection
- 4) Revision following failed radial head arthroplasty

The long stem is for single cemented use only. The short stem coated with titanium plasma-spray is for single use with or without cement.



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10) Summary of technological characteristics

The only change to the cleared devices of the *Salto Talaris Total Ankle Prosthesis* and the *RHS* is the addition of a new coating subcontractor: Eurocoating S.p.A

The Eurocoating S.p.A coating has the same specifications currently requested from BioCoat Company: coating specification drawings as well as the intended use of the coating of the implants concerned are not modified compared to the already cleared devices.

Process specifications for the application of titanium coating have been provided in Eurocoating S.p.A Master File MAF 1989.

The indications for use, the other technical characteristics (design, materials, manufacturing, sizing, method of fixation) of the *Salto Talaris Total Ankle Prosthesis* and the *RHS* are identical to the predicate devices. The covered zones of the implants concerned remain the same ones

11) Non-clinical testing & Substantial equivalence conclusion

Non-clinical testing (shear fatigue strength, static shear strength test, static tensile strength and abrasion) and coating characterization (thickness, pore size and pore volume) were performed to determinate substantial equivalence.

The design, the material, the sizes, the method of fixation and the sterilization process are identical for both devices whatever the coating subcontractor is.

The results of this evaluation allow us to conclude that the proposed new coating subcontractor Eurocoating S.p.A described in this submission does not induce any new or higher risk compared to the predicate coating subcontractor BioCoat Company and therefore both coating subcontractors (proposed and predicate) are substantially equivalent.





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Tornier SAS
% Ms. Séverine Bonneton
Project Regulatory Affairs Coordinator
161, Rue Lavoisier
38330 Montbonnot Saint Martin
France

Letter dated: May 17, 2013

Re: K130533

Trade/Device Name: Salto Talaris Total Ankle Prosthesis RHS
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSN, JDB, KWI
Dated: April 18, 2013
Received: April 19, 2013

Dear Ms. Bonneton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130533

Device Name: Salto Talaris Total Ankle Prosthesis
RHS

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Prescription Use ☒ X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices